Claim 23, line 3, cancel "in" and substitute -- with --.

R E M A R K S

Applicants express the appreciation to Examiner Doyle for the courtesy of the personal interview held on November 14, 1991, the substance of which is recorded in the Examiner's Interview Summary Record of that same date.

During the interview, the rejections in the Office Action of July 10, 1991 were discussed, including the substance of U.S. patents cited as prior art references of Bartolomeo, Ray, Hayes and Oldham et al. The substance of what has been submitted as claim 43 was discussed in detail along with reasons why it is believed that the subject matter of that claim is not anticipated or obvious in view of the cited references.

Claims 1-11 have been cancelled and replaced by claims 43-52. Claims 12-21, 23-26 remain in the case, with amendments to claims 12, 17, 18, 19, 20, 21 and 23. The rejections made by the Examiner based on 35 USC § 112, second paragraph, are believed to have been overcome by the amendments mentioned above.

As discussed during the interview, the invention which is the subject of this application and defined in the pending claims is the latest in the developmental efforts for an oral nicotine delivery system which is a cigarette substitute. Original developments are reflected in U.S. patents 4,284,089; 4,736,755; 4,793,366; 4,800,903 and 4,813,437, which are now owned by the entity which owns the present application.

As discussed, the developmental work began in 1977 and progressed through various product stages until a product was introduced into the market place which had a polyethylene plug containing 10-15 milligrams of nicotine and packaged in a polyethylene material having a shelf life of two weeks to thirty days. After the Food & Drug Administration pulled the product off

the market as being a new drug, further developmental work resulted in the invention of this application which is believed to have a significantly longer shelf life, up to two years in length.

The reason for this extended shelf life is due to the discovery of maintaining the nicotine in the container in the absence of oxygen, and finding a material which is essentially impermeable to both nicotine and oxygen, from which a container or cartridge is formed. It is submitted that nowhere in the prior art is this concept shown or even suggested, as discussed below.

As set forth in the two independent claims now in the application, claims 43 and 12, the important features of the invention are providing a container formed of a material which is effectively impermeable to nicotine and oxygen, with a carrier in the container for carrying a measured amount of nicotine in a state which can supply nicotine in vapor form to the user. The carrier is maintained in the container in a effectively oxygen-free environment. The container includes at least one portion through which nicotine in the carrier is accessible to the user and which can be selectively opened to allow a measured amount of nicotine to be released to the user upon the application of a differential pressure.

The primary cited reference is U.S. patent 2,860,638 to Bartolomeo. While at first this reference might appear to be significant, it is not sufficient in forming a basis for rejecting the present claims. For example, nicotine is mentioned as being contained in a capsule by absorbing it into a cotton reservoir. This has been found not to be workable by the inventors since cotton will not hold nicotine and release it in vapor form. Secondly, there is no material mentioned or suggested which could operate as a nicotine and oxygen impermeable barrier for maintaining the nicotine in an oxygen-free environment. It is mentioned that the capsule could be formed from two co-acting

plastic half-sections which are hermetically sealed. It is also mentioned that the capsule could be provided with opposed heat sealed or crimped ends to provide a hermetically sealed tube.

As mentioned during the interview, it was discovered that nicotine is such a volatile substance that crimp sealing would not work and that the only polymer found to work is an amorphous copolymer of acrylonitrile and methyl acrylate which, as discussed below, is not obvious from earlier known uses of that copolymer. Thus, there is no teaching in Bartolomeo of a container for nicotine which can be released in vapor form, which is effectively impermeable to nicotine and oxygen. Neither is the importance of maintaining nicotine in an oxygen-free environment taught. It was found by the inventors that even a small amount of oxygen in a cartridge would cause the nicotine to oxidize over time and turn into a sticky brown mass which is undesirable for the product as claimed. Thus, the claims also recite maintaining the nicotine reservoir or carrier in an effectively nicotine-free environment.

None of the other patents teach the importance of an oxygen-free environment. Although U.S. patent 4,736,755 to Oldham et al mentions the use of an anti-oxidant to be added to the nicotine, as explained, this was done as a flavor enhancer and not to form an oxygen-free environment. In fact, it was shown that while the product in that patent worked for its intended purpose because nicotine was releasable from a carrier, the shelf life was not acceptable for a commercial product.

The Examiner also cited the teachings of U.S. patent 4,265,948 to Hayes et al for the use of a copolymer of acrylonitrile and methyl acrylate for a container for volatile oils which are used in perfumes and flavorings. It is submitted that this teaching falls short of rendering the claimed invention obvious because there is no teaching of the copolymer being impervious to nicotine and, in fact, because of the screw-on cap and crimped end of the tube in

that patent, that tube would not be effectively impermeable to nicotine because of the volatile nature of the substance. As mentioned in the patent application, the invention maintains its long shelf life because of its ability to maintain an oxygen-free environment and to contain nicotine in the container. When a copolymer such as acrylonitrile and methyl acrylate is used, the container must be heat sealed, since nicotine will escape through the small openings caused by crimping or around the screw-on cap. For this reason, aluminum foil which is not sealed shut has turned out not to be a suitable container material.

None of the other references is considered to be as relevant as the ones discussed above, so no further discussion of them is deemed necessary.

Therefore, for the foregoing reasons, it is submitted that the invention in the claims presently in the application patentably distinguish over the cited references.

The dependent claims all recite additional features of the invention. They will not be discussed in detail since it is believed that the independent claims contain patentable subject matter.

In view of the foregoing, it is submitted that the claims are now in condition for allowance.

Respectfully submitted,

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CERTIFICATE UNDER 37 C.F.R. 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on 1/8, 1992.

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